



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,346	01/31/2001	Suggy S. Chrai	176650-96	2597

7590 08/27/2002

William Squire  
Carella, Byrne, Bain, Gilfillan, Cecchi,  
Stewart & Olstein  
6 Becker Farm Road  
Roseland, NJ 07068

EXAMINER

WILLIAMSON, MICHAEL A

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/27/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/774,346

Applicant(s)

CHRAI ET AL.

Examin r

Michael A. Williamson

Art Unit

1616

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 17-19 and 21-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17-19 and 21-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1616

## **DETAILED ACTION**

### ***Pending Claims***

The pending claims in the instant application are 1-10, 17-19 and 21-35. The independent claims are 1, 18 and 33.

### ***Claim Rejections - 35 USC § 102***

1. The rejection of claims 1-10, 17-19 and 21-35 under 35 U.S.C. 102(b) as being anticipated by Mlodozieniec (U.S. Patent 4,332,789) has been withdrawn in view of Applicant's amendments.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-10, 17-19 and 21-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozieniec (U.S. Patent 4,332,789).

Art Unit: 1616

Mlodozeniec generically discloses a product comprising a package which is a container and a plurality of solid, discrete pharmaceutical or diagnostic unit forms that are physically separated and independent of each other and in the form of a diagnostic reagent, a tablet, a caplet, a powder, or a capsule wherein each unit dosage form includes at least one active ingredient in an amount which does not vary from a predetermined target amount by more than 5 weight percent. The unit forms are attached to a planar base thermoplastic substrate film, covered by a second planar thermoplastic film and surrounded by a bond that joins the substrate film and the cover film. The ingestible thermoplastics are polyvinylacetate, hydroxypropylmethylcellulose, polyethylene oxide, polypropylene, polyester or polyamide. Mlodozeniec also discloses that the package may include multiple layers of unit forms. Mlodozeniec further discloses that optical scanning may be used in determining the amount of active ingredient (see Abstract, Fig. 6a-6d, col. 4, lines 21-31, col. 6, lines 13-21, col. 7, lines 33-44, col. 12, line 21 through col. 13, line 25, col. 13, lines 36-66, col. 16, lines 25-32, col. 16, line 57 through 68, col. 24, line 27 through col. 26, line 26 and col. 33, line 50 through col. 35, line 15). Mlodozeniec

Art Unit: 1616

does not specifically disclose a substrate and a plurality of discrete pharmaceutical or diagnostic unit dosage forms.

Mlodozeniec does generically disclose packaging in blister packs (see col. 4, lines 25-31). The advantage of blister packs is cost savings in handling and equipment. Therefore, it would have been obvious to one of ordinary skill in the art to use the combined teaching of Mlodozeniec to make a product comprising a substrate and a plurality of discrete pharmaceutical or diagnostic unit dosage forms associated with the substrate in the absence of a factual showing to the contrary or a showing of unexpected results. Additionally, with regard to the recitation of a plurality of semi-spherical bubbles or a deposit having a substantially spherical shape, Mlodozeniec discloses that the cover forms a "basket shape" over the unit forms (see Figs. 6). A change in size or in shape in the absence of a change in function does not impart patentability (see *In re Rose*, 220 F.d2 459, 105 USPQ 237 (CCPA 1955) and/or *In re Dailey*, 357 F.d 669, 149 USPQ 47 (CCPA 1966)).

#### ***Double Patenting***

4. The rejection of claims 36 and 37 under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of prior U.S. Patent No. 6,303,143 has been

Art Unit: 1616

withdrawn in view of Applicant's amendments which included the deletion of claims 36 and 37.

***Response to Arguments***

5. Applicant's arguments with respect to claims 1-10, 17-19 and 21-35 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Art Unit: 1616

7.

### Crystal Mall 1 Facsimile Center

A facsimile center has been established in Crystal Mall 1, room 7C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 308-4556. The new location should be used in all instances when faxing any correspondence to Group 1600. Use of the new Crystal Mall 1 center will facilitate rapid delivery of materials to the Group. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989).

8. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Michael A. Williamson whose telephone number is (703) 308-1235.

  
S. MARK CLARDY  
PATENT EXAMINER  
GROUP 1200 1616

Williamson020826  
August 26, 2002